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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/760,819

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Christopher J. Stanley

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11/29/2006

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/760,819 | Applicant(s) STANLEY, CHRISTOPHER J. | |
| | Examiner Frank W Lu | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-18,20,23-26 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-18,20,23-26 and 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2001 (original) is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/313,385.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on September 14, 2006 has been entered. The claims pending in this application are claims 1, 3-18, 20, 23-26, and 28-38. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on September 14, 2006.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Scope of Enablement

Claims 1, 3-17, 20, 23-26, and 28-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for performing the methods recited in 1, 3-17, 20, 23-26, and 28-38 when said carrier macromolecule is dextran, does not reasonably provide enablement for performing the methods recited in 1, 3-17, 20, 23-26, and 28-38 when said carrier macromolecule is any kind of polysaccharide or any kind of dextran derivative. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the

quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that the methods recited in 1, 3-17, 20, 23-26, and 28-38 can be performed when said carrier macromolecule is any kind of polysaccharide or any kind of dextran derivative. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether the methods recited in 1, 3-17, 20, 23-26, and 28-38 can be performed when said carrier macromolecule is any kind of polysaccharide or any kind of dextran derivative.

Claims 1, 3-17, 20, 23-26, and 28-38 are directed to a process for the amplification of a nucleic acid template wherein said carrier macromolecule is any kind of polysaccharide or any kind of dextran derivative. Although the specification provides a guidance for labeling an oligonucleotide primer with a dextran (see the specification, page 14, Example 1), since the specification does not provide a guidance to show how a nucleic acid can be labeled with any kind of polysaccharide or any kind of dextran derivative such as starch, glycogen, and cellulose and art search cannot locate references related to a method for labeling a nucleic acid with starch, glycogen, and cellulose, in view of claims 1, 3-17, 20, 23-26, and 28-38, it is unclear how a primer recited in claims 1, 3-17, 20, 23-26, and 28-38 can bind to any kind of polysaccharide or any kind of dextran derivative such as starch, glycogen, and cellulose so that the methods recited in 1, 3-17, 20, 23-26, and 28-38 cannot be performed. Furthermore, although a polysaccharide

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and a dextran or its derivative can be labeled to a fluorescent dye, since claims 35 and 37 do not limit a label to a specific label, it is unclear whether any kind of label can be used to label a polysaccharide and a dextran or its derivative.

With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether a nucleic acid can be labeled with any kind of polysaccharide or any kind of dextran derivative such as starch, glycogen, and cellulose.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-17, 20, 34, 37, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 3 is rejected as vague and indefinite. Since the claim does not indicate that divinyl sulfone is located on a primer or a non-nucleotide carrier macromolecule, it is unclear how to bind a primer to a non-nucleotide carrier macromolecule via one or more moieties derived from divinyl sulfone. Please clarify.

7. Claim 34 recites the limitation "homopolyamino acid" in the claim. There is insufficient antecedent basis for this limitation in the claim because claim 3 requires that said carrier macromolecule is only selected from the group consisting of a polysaccharide and a dextran or dextran derivative. Please clarify.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy *et al.*, (US Patent No. 5,648,213, filed on August 30, 1994).

Regarding claim 18, since it is known that cellulose is a complex carbohydrate, or polysaccharide consisting of 3,000 or more glucose units and glucose has a formula of (C₆H₁₂O₆) with a molecular weight of 180.2 Daltons (see an attachment for cellulose in previous office action mailed on January 7, 2004), Reddy *et al.*, teach providing a first nucleic acid (ie., a first oligonucleotide) bound to a non- nucleotide carrier macromolecule (ie., a first immunoreagent), providing a second nucleic acid (ie., a second oligonucleotide) bound to a non-nucleotide carrier macromolecule (ie., a support such as cellulose slurry) wherein said non-nucleotide carrier macromolecule has a molecular weight in excess of 100,000 Daltons (ie., $3,000 \times 180.2 = 540,600$ Daltons for cellulose), contacting said first and second nucleic acids under hybridization conditions, and detecting hybridization between said first and second nucleic acids (see claim 2 in columns 39 and 40 and column 8, lines 45-65).

Reddy *et al.*, do not disclose providing a first nucleic acid bound to a non-nucleotide carrier macromolecule wherein said non-nucleotide carrier macromolecule has a molecular

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weight in excess of 100,000 Daltons. However, Reddy *et al.*, teach that an immunoreagent is a protein comprising more than 50 amino acids (see column 2, lines 30-52).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 18 using a first nucleic acid bound to a non-nucleotide carrier macromolecule wherein said non-nucleotide carrier macromolecule has a molecular weight in excess of 100,000 Daltons in view of the prior art of Reddy *et al.*. One having ordinary skill in the art would have been motivated to select a protein having a molecular weight in excess of 100,000 Daltons (ie., a protein with more than 835 amino acids and we consider average molecular weight for an amino acid is equal to 120 Daltons) as the first immunoreagent of the claim because Reddy *et al.*, suggest that any protein comprising more than 50 amino acids is used as an immunoreagent (see column 2, lines 30-52). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to perform the method recited in claim 18 using a first nucleic acid bound to a non-nucleotide carrier macromolecule wherein said non-nucleotide carrier macromolecule has a molecular weight in excess of 100,000 Daltons (ie., a protein with more than 835 amino acids).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

November 22, 2006



FRANK LU
PRIMARY EXAMINER